

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

ELIZABETH WOHLBERG,

*

Plaintiff,

*

v.

*

Civil Action No. GLR-20-2093

ETHICON, INC., et al.,

*

Defendants.

*

MEMORANDUM OPINION

THIS MATTER is before the Court on the Motion for Partial Dismissal of Plaintiff's Complaint for Failure to State a Claim by Defendants Ethicon, Inc. ("Ethicon") and Johnson & Johnson ("J&J") (together, "Ethicon" or "Defendants") (ECF No. 4). The Motion is ripe for disposition, and no hearing is necessary. See Local Rule 105.6 (D.Md. 2018). For the reasons outlined below, the Court will grant the Motion.

I. BACKGROUND

Defendants Ethicon and J&J manufacture and sell pelvic mesh products, including Gynecare TVT-O ("Gynecare"), which is used for the treatment of stress urinary incontinence. (See Compl. ¶¶ 12–18, ECF No. 1). Plaintiff Elizabeth Wohlberg suffers from stress urinary incontinence. (Id. ¶ 20). On December 19, 2013, Wohlberg underwent surgery at Greater Baltimore Medical Center in Towson, Maryland for the implantation of the Gynecare device to treat her stress urinary incontinence. (Id. ¶¶ 19, 20). Over time, the Gynecare implant became inflamed, causing Wohlberg to suffer chronic pain and dyspareunia. (Id. ¶ 21). As a result, Wohlberg underwent a revision surgery at Sinai

Hospital in Baltimore, Maryland on August 30, 2017. (Id.). Because of the complications associated with her Gynecare implant, Wohlberg has experienced significant mental and physical pain, sustained permanent injury and physical deformity, and suffered financial loss. (Id. ¶ 22).

Wohlberg filed her Complaint against Defendants on July 17, 2020. (ECF No. 1). Wohlberg’s eleven-count Complaint alleges: strict liability for failure to warn (Count I); strict liability for design defect (Count II); negligence (Count III); negligent misrepresentation (Count IV); breach of express warranty (Count V); breach of implied warranty (Count VI); violation of consumer protection laws (Count VII); fraud (Count VIII); unjust enrichment (Count IX); gross negligence (Count X); and punitive damages (Count XI). (Compl. ¶¶ 36–169). Wohlberg seeks monetary damages. (Id. at 35–36).

Defendants filed their Partial Motion to Dismiss on September 16, 2020. (ECF No. 4). On September 30, 2020, Wohlberg filed her Opposition. (ECF No. 7). Defendants filed a Reply on October 14, 2020. (ECF No. 10).

II. DISCUSSION

A. Standard of Review

The purpose of a Rule 12(b)(6) motion is to “test[] the sufficiency of a complaint,” not to “resolve contests surrounding the facts, the merits of a claim, or the applicability of defenses.” King v. Rubenstein, 825 F.3d 206, 214 (4th Cir. 2016) (quoting Edwards v. City of Goldsboro, 178 F.3d 231, 243 (4th Cir. 1999)). A complaint fails to state a claim if it does not contain “a short and plain statement of the claim showing that the pleader is entitled to relief,” Fed.R.Civ.P. 8(a)(2), or does not “state a claim to relief that is plausible

on its face,” Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007)). A claim is facially plausible “when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” Id. (citing Twombly, 550 U.S. at 556). “Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice.” Id. (citing Twombly, 550 U.S. at 555). Though the plaintiff is not required to forecast evidence to prove the elements of the claim, the complaint must allege sufficient facts to establish each element. Goss v. Bank of Am., N.A., 917 F.Supp.2d 445, 449 (D.Md. 2013) (quoting Walters v. McMahan, 684 F.3d 435, 439 (4th Cir. 2012)), aff’d, 546 F.App’x 165 (4th Cir. 2013).

In considering a Rule 12(b)(6) motion, a court must examine the complaint as a whole, consider the factual allegations in the complaint as true, and construe the factual allegations in the light most favorable to the plaintiff. Albright v. Oliver, 510 U.S. 266, 268 (1994); Lambeth v. Bd. of Comm’rs, 407 F.3d 266, 268 (4th Cir. 2005) (citing Scheuer v. Rhodes, 416 U.S. 232, 236 (1974)). But, the court need not accept unsupported or conclusory factual allegations devoid of any reference to actual events, United Black Firefighters v. Hirst, 604 F.2d 844, 847 (4th Cir. 1979), or legal conclusions couched as factual allegations, Iqbal, 556 U.S. at 678.

B. Analysis

Defendants move to dismiss in part Wohlberg's negligence claim.¹ Wohlberg responds that her Complaint adequately states a claim for negligence, but in the event the Court finds it does not, Wohlberg should be permitted to file an amended complaint. The Court addresses these arguments in turn.

1. Negligence Claim

Defendants argue that Wohlberg's negligence claim should be dismissed to the extent it asserts a claim for negligent manufacturing defect because Wohlberg does not identify how her Gynecare implant deviated from Ethicon's design specifications.² The Court agrees.

To state a claim for manufacturing defect under Maryland law, a plaintiff must allege facts establishing that the product at issue either was not manufactured in accordance with the product's design specifications or that some other error occurred during the manufacturing process. Shreve v. Sears, Roebuck & Co., 166 F.Supp.2d 378, 411 (D.Md. 2001) (citing Singleton v. Int'l Harvester Co., 685 F.2d 112, 114 (4th Cir. 1981)); see also Phipps v. Gen. Motors Corp., 363 A.2d 955, 959 (Md. 1976) (concluding that a

¹ Defendants also move to dismiss Wohlberg's claims for breach of express warranty (Count V), breach of implied warranty (Count VI), violation of consumer protection statutes (Count VII), and fraud (Count VIII). Wohlberg states that she does not oppose dismissal of these claims. (Pl.'s Resp. Opp'n Defs.' Rule 12(b)(6) Mot. Partial Dismissal ["Opp'n"] at 1, 7, ECF No. 7). Accordingly, these claims will be dismissed.

² Wohlberg appears to concede that she does not intend to bring a manufacturing defect claim, stating that her negligence claim "is for ordinary negligence, and is not a claim for negligent manufacturing defect." (Opp'n at 6). Nonetheless, the Court will consider whether Wohlberg's Complaint states a cognizable claim for negligent manufacturing defect.

manufacturing defect results when “the defect is a result of an error in the manufacturing process, that is where the product is in a condition not intended by the seller”). Because a manufacturing defect claim focuses on the conduct or procedures involved in the manufacturing process, it is insufficient to simply allege “that the product [was] defective at the time it left the manufacturer’s control.” Shreve, 166 F.Supp.2d at 411.

In Count III of her Complaint, Wohlberg broadly asserts that Defendants breached their duties with respect to the “manufacture, design, labeling, warnings, instructions, sale, marketing, distribution, and recruitment and training of physicians to implant the [Gynecare implant].” (Compl. ¶ 59) (emphasis added). Wohlberg does not, however, identify any specific defect in the manufacturing process of her Gynecare implant that proximately caused her injuries, nor does she allege how the Gynecare implant departed from Ethicon’s intended design specifications for the device. Without alleging these facts, Wohlberg cannot proceed with a manufacturing defect claim. See Figueroa v. Ethicon, Inc., No. 2:19-CV-01188 KWR/KRS, 2020 WL 1434249, at *3 (D.N.M. Mar. 24, 2020) (dismissing manufacturing defect claims due to plaintiff’s “fail[ure] to allege that the mesh deviated from Defendants’ design specifications”); Kuchenbecker v. Johnson & Johnson, No. 19-61712-CIV, 2019 WL 4416079, at *2 (S.D.Fla. Sept. 16, 2019) (“[T]he Complaint fails to specify how the device implanted in the Plaintiff deviated from manufacturing specifications. Without more, the Court simply cannot draw the reasonable inference that Defendants defectively manufactured the [device] that was implanted in the Plaintiff.”). Accordingly, to the extent Wohlberg attempts to allege a negligent manufacturing defect claim, this claim must be dismissed.

2. Leave to Amend

Having found that Wohlberg's negligence claim must be dismissed in part, the Court next considers whether she is entitled to amend her Complaint. Wohlberg argues that the Court should "permit her an opportunity to amend her complaint to address any deficiencies identified by the Court." (Pl.'s Resp. Opp'n Defs.' Rule 12(b)(6) Mot. Partial Dismissal ["Opp'n"] at 7, ECF No. 7). At this juncture, the Court is not persuaded.

A party may amend its complaint once as a matter of course within twenty-one days of serving it or within twenty-one days after the defendant files a motion to dismiss. Fed.R.Civ.P. 15(a)(1). For all other circumstances, "a party may amend its pleading only with the opposing party's written consent or the court's leave." Fed.R.Civ.P. 15(a)(2). When seeking leave to amend from this Court, a party must submit a copy of the proposed amended complaint as well as a red-lined comparison to the initial complaint. See Local Rule 103.6(a), (c) (D.Md. 2018). In general, a "court should freely give leave when justice so requires." Fed.R.Civ.P. 15(a)(2). Importantly, though, justice does not require permitting leave to amend when amendment would prejudice the opposing party, the moving party has exhibited bad faith, or amendment would be futile. See Edell & Assocs., P.C. v. Law Offices of Peter G. Angelos, 264 F.3d 424, 446 (4th Cir. 2001) (citing Edwards v. City of Goldsboro, 178 F.3d 231, 242 (4th Cir. 1999)).

Here, Wohlberg had twenty-one days after the filing of Defendants' Motion to correct any deficiencies in her Complaint without seeking leave from the Court. Now that such time has passed, Wohlberg must seek leave to amend her Complaint. Wohlberg has not, however, set forth any reasons why amendment is justified. Wohlberg has also failed

to provide a copy of any proposed amended complaint as required by the Local Rules. Without Wohlberg's justification for her proposed amendments or a copy of the proposed amended complaint, the Court is unable to determine whether amendment is warranted. As such, the Court declines to grant Wohlberg leave to amend her Complaint at this time.³

III. CONCLUSION

For the foregoing reasons, Defendants' Motion for Partial Dismissal of Plaintiff's Complaint for Failure to State a Claim (ECF No. 4) will be granted. A separate Order follows.

Entered this 19th day of April, 2021.

/s/
George L. Russell, III
United States District Judge

³ Of course, Wohlberg remains free to seek Defendants' written consent to amend her Complaint or formally move the Court for leave to amend in accordance with the Local Rules.